

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS 5-HT₁ AGONISTS, COMBINATIONS (ALL DOSAGE FORMS)

BRAND NAME
(generic)

AMERGE
(naratriptan)

AXERT
(almotriptan)

FROVA
(frovatriptan)

IMITREX
(sumatriptan)

MAXALT/MAXALT-MLT
(rizatriptan)

ONZETRA XSAIL
(sumatriptan)

RELPAX
(eletriptan)

SUMAVEL DosePro
(sumatriptan)

TOSYMRA
(sumatriptan)

TREXIMET
(sumatriptan/naproxen)

ZEMBRACE SYMTOUCH
(sumatriptan)

ZOMIG / ZOMIG-ZMT
(zolmitriptan)

Status: CVS Caremark Criteria

Type: Post Limit Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Amerge

Amerge is indicated for the acute treatment of migraine with or without aura in adults.

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Amerge, reconsider the diagnosis of migraine before Amerge is administered to treat any subsequent attacks. Amerge is not indicated for the prevention of migraine attacks. Safety and effectiveness of Amerge have not been established for cluster headache.

Axert

Adults: Axert (almotriptan malate) is indicated for the acute treatment of migraine attacks in patients with a history of migraine with or without aura.

Adolescents Age 12 to 17 Years: Axert is indicated for the acute treatment of migraine headache pain in patients with a history of migraine attacks with or without aura usually lasting 4 hours or more (when untreated).

Axert should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Axert, the diagnosis of migraine should be reconsidered before Axert is administered to treat any subsequent attacks. In adolescents age 12 to 17 years, efficacy of Axert on migraine-associated symptoms (nausea, photophobia, and phonophobia) was not established. Axert is not intended for the prophylactic therapy of migraine or for use in the management of hemiplegic or basilar migraine. Safety and effectiveness of Axert have not been established for cluster headache which is present in an older, predominantly male population.

Frova

Frova tablets are indicated for the acute treatment of migraine attacks with or without aura in adults.

Use only if a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Frova, reconsider the diagnosis of migraine before Frova is administered to treat any subsequent attacks. Frova is not indicated for the prevention of migraine attacks. Safety and effectiveness of Frova have not been established for cluster headache.

Imitrex Injection

Imitrex Injection is indicated in adults for (1) the acute treatment of migraine, with or without aura, and (2) the acute treatment of cluster headache.

Use only if a clear diagnosis of migraine or cluster headache has been established. If a patient has no response to the first migraine or cluster headache attack treated with Imitrex Injection, reconsider the diagnosis before Imitrex Injection is administered to treat any subsequent attacks. Imitrex is not indicated for the prevention of migraine or cluster headache attacks.

Imitrex Nasal Spray and Imitrex Tablets

Imitrex Nasal Spray and Imitrex Tablets are indicated for the acute treatment of migraine with or without aura in adults.

Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Imitrex, reconsider the diagnosis of migraine before Imitrex is administered to treat any subsequent attacks. Imitrex is not indicated for the prevention of migraine attacks. Safety and effectiveness of Imitrex nasal spray and Imitrex tablets have not been established for cluster headache.

Maxalt-MLT and Maxalt

Maxalt-MLT and Maxalt are indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 6 to 17 years old.

Maxalt should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Maxalt, the diagnosis of migraine should be reconsidered before Maxalt is administered to treat any subsequent attacks. Maxalt is not indicated for use in the management of hemiplegic or basilar migraine. Maxalt is not indicated for the prevention of migraine attacks. Safety and effectiveness of Maxalt have not been established for cluster headache.

Onzetra Xsail

Onzetra Xsail is indicated for the acute treatment of migraine with or without aura in adults.

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Onzetra Xsail, reconsider the diagnosis of migraine before treatment of subsequent attacks with Onzetra Xsail. Onzetra Xsail is not indicated for the prevention of migraine attacks. Safety and effectiveness of Onzetra Xsail have not been established for the treatment of cluster headache.

Relpax

Relpax tablets are indicated for the acute treatment of migraine attacks with or without aura in adults.

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Relpax, reconsider the diagnosis of migraine before treatment of subsequent attacks with Relpax. Relpax is not indicated for the prevention of migraine attacks. Safety and effectiveness of Relpax have not been established for the treatment of cluster headache.

Sumavel DosePro

Sumavel DosePro is indicated in adults for (1) the acute treatment of migraine, with or without aura, and (2) the acute treatment of cluster headache.

Use only if a clear diagnosis of migraine or cluster headache has been established. If a patient has no response to the first migraine attack treated with Sumavel DosePro, reconsider the diagnosis of migraine before Sumavel DosePro is administered to treat any subsequent attacks. Sumavel DosePro is not indicated for the prevention of migraine attacks.

Tosymra

Tosymra is indicated for the acute treatment of migraine with or without aura in adults.

Limitations of Use:

- Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Tosymra, reconsider the diagnosis before Tosymra is administered to treat any subsequent attacks.
- Tosymra is not indicated for the preventive treatment of migraine.
- Tosymra is not indicated for the treatment of cluster headache.

Treximet

Treximet is indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

Use only if a clear diagnosis of migraine headache has been established. If a patient has no response to the first migraine attack treated with Treximet, reconsider the diagnosis of migraine before Treximet is administered to treat any subsequent attacks. Treximet is not indicated for the prevention of migraine attacks. Safety and effectiveness of Treximet have not been established for cluster headache.

Zembrace SymTouch

Zembrace SymTouch is indicated for the acute treatment of migraine with or without aura in adults.

Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Zembrace SymTouch, reconsider the diagnosis before Zembrace SymTouch is administered to treat any subsequent attacks. Zembrace SymTouch injection is not indicated for the prevention of migraine attacks.

Zomig Nasal Spray

Zomig Nasal Spray is indicated for the acute treatment of migraine with or without aura in adults and pediatric patients 12 years of age and older.

Only use Zomig if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache. Not recommended in patients with moderate or severe hepatic impairment.

Zomig Tablets and Zomig-ZMT

Zomig is indicated for the acute treatment of migraine with or without aura in adults.

Zomig should only be used if a clear diagnosis of migraine has been established. If a patient has no response to Zomig treatment for the first migraine attack, reconsider the diagnosis of migraine before Zomig is administered to treat any subsequent attacks. Zomig is not indicated for the prevention of migraine attacks. Safety and effectiveness of Zomig have not been established for cluster headache.

Compendial Uses¹⁶

Imitrex Nasal Spray

Acute treatment of cluster headache

Onzetra Xsail

Acute treatment of cluster headache

Tosymra

Acute treatment of cluster headache

Zomig Nasal Spray

Acute treatment of cluster headache

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient does not have confirmed or suspected cardiovascular or cerebrovascular disease, or uncontrolled hypertension

AND

- The patient has a diagnosis of migraine headache AND
 - The patient is currently using migraine prophylactic therapy or unable to take migraine prophylactic therapies due to inadequate response, intolerance or contraindication
[Note: examples of prophylactic therapy are divalproex sodium, topiramate, valproate sodium, metoprolol, propranolol, timolol, atenolol, nadolol, amitriptyline, venlafaxine.]

AND

- Medication overuse headache has been considered and ruled out

OR

- The request is for sumatriptan injection, sumatriptan nasal spray, or zolmitriptan nasal spray (e.g., Imitrex Injection, Imitrex Nasal Spray, Onzetra Xsail, Sumavel DosePro, Tosymra, Zomig NS) for the treatment of cluster headache

Quantity Limits apply.

POST LIMIT QUANTITY

PLEASE NOTE: Since manufacturer package sizes may vary, it is the discretion of the dispensing pharmacy to fill quantities per package size up to these quantity limits. In such cases the filling limit and day supply may be less than what is indicated.

Medication	Strength	Maximum dose per 24 hours	1 Month Limit *	3 Months Limit *
Amerge (naratriptan)	1 mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days
	2.5 mg	2 tablets 5 mg		
Axert (almotriptan)	6.25 mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days
	12.5 mg	2 tablets 25 mg		
Frova (frovatriptan)	2.5 mg	3 tablets 7.5 mg	27 tablets / 25 days	81 tablets / 75 days
Imitrex Injection (sumatriptan) single dose vials	6 mg	2 injections 12 mg	18 vials (9mL) / 25 days	55 vials (27.5mL) / 75 days
Imitrex Injection (sumatriptan) syringes STATdose / Refill	4 mg	3 injections 12 mg	27 syringes (13.5mL) / 25 days	81 syringes (40.5mL) / 75 days
	6 mg	2 injections 12 mg	18 syringes (9mL) / 25 days	54 syringes (27mL) / 75 days
Imitrex Nasal Spray (sumatriptan)	5 mg	4 sprays**	36 units / 25 days	108 units / 75 days
	20 mg	2 sprays 40 mg	18 units / 25 days	54 units / 75 days
Imitrex Tablets (sumatriptan)	25mg, 50mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days
	100 mg	2 tablets 200 mg		
Maxalt Maxalt-MLT (rizatriptan)	5 mg	3 tablets**	27 tablets / 25 days	81 tablets / 75 days
	10 mg	3 tablets 30 mg		

Onzetra Xsail (sumatriptan)	11mg	4 nosepieces 44mg	32 nosepieces / 25 days (2 kits, 16 pouches)	96 nosepieces / 75 days (6 kits, 48 pouches)
Relpax (eletriptan)	20 mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days
	40 mg	2 tablets 80 mg		
Sumavel DosePro (sumatriptan)	4 mg	3 injections 12 mg	27 injections (13.5mL) / 25 days	81 injections (40.5mL) / 75 days
	6 mg	2 injections 12 mg	18 injections (9mL) / 25 days	54 injections (27mL) / 75 days
Tosymra (sumatriptan)	10 mg	3 sprays 30 mg	24 units / 25 days	72 units / 75 days
Treximet (sumatriptan/naproxen)	10mg/60mg	1 tablet**	18 tablets / 25 days	27 tablets / 75 days
	85mg/500mg	1-2 tablets 170mg/1000mg	18 tablets / 25 days	54 tablets / 75 days
Zembrace SymTouch (sumatriptan)	3 mg	4 injections 12mg	36 autoinjectors (18mL) / 25 days	108 autoinjectors (54mL) / 75 days
Zomig Nasal Spray (zolmitriptan)	2.5 mg	2 sprays**	18 units / 25 days	54 units / 75 days
	5 mg	2 sprays 10 mg		
Zomig Tablets Zomig-ZMT (zolmitriptan)	2.5 mg	2 tablets**	18 tablets / 25 days	54 tablets / 75 days
	5 mg	2 tablets 10 mg		
* The duration of 25 days is used for a 30-day fill period and 75 days is used for a 90-day fill period to allow time for refill processing.				
*The limit criteria apply to both brand and generic, if available.				
**Utilize higher strength available.				

REFERENCES

1. AmERGE [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2016.
2. Axert [package insert]. Titusville, NJ: Ortho-McNeil Pharmaceutical, Inc.; April 2018.
3. Frova [package insert]. Chadds Ford, PA: Endo Pharmaceuticals Inc.; February 2018.
4. Imitrex Injection [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
5. Imitrex Nasal Spray [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
6. Imitrex Tablets [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
7. Maxalt and Maxalt-MLT [package insert]. Whitehouse Station, NJ: Merck & Co., Inc; March 2016.
8. Onzetra Xsail [package insert]. Aliso Viejo, CA: Avanir Pharmaceuticals, Inc.; January 2016.
9. Relpax [package insert]. New York, NY: Pfizer, Inc.; February 2018.
10. Sumavel DosePro [package insert]. Malvern, PA: Endo Pharmaceuticals Inc.; June 2016.
11. Tosymra [package insert]. Princeton, NJ: Promius Pharma, LLC; January 2019.
12. Treximet [package insert]. Morristown, NJ: Pernix Therapeutics, LLC; November 2017.
13. Zembrace SymTouch [package insert]. Princeton, NJ: Promius Pharma LLC; March 2017.
14. Zomig Nasal Spray [package insert]. Hayward, CA: Impax Pharmaceuticals Inc.; May 2019.
15. Zomig Tablets and Zomig-ZMT [package insert]. Hayward, CA: Impax Pharmaceuticals Inc.; May 2019.
16. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed June 2019.
17. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed June 2019.
18. Beithon J, Gallenberg M, Johnson K, et al. Institute for Clinical Systems Improvement. Diagnosis and Treatment of Headache. https://www.icsi.org/_asset/qwrznq/Headache.pdf. Updated January 2013. Accessed May 2016.
19. Silberstein S, Holland S, Freitag F, et al. Evidence-Based Guideline Update: Pharmacologic Treatment for Episodic Migraine Prevention in Adults: Report of the Quality and the American Headache Society Standards Subcommittee of the American Academy of Neurology. *Neurology* 2012;78;1337-1346.
20. Lewis D, Ashwal S, Hershey A, et al. Practice Parameter: Pharmacological treatment of migraine headache in children and adolescents: Report of the American Academy of Neurology Quality Standards Subcommittee and the Practice Committee of the Child Neurology Society. *Neurology* 2004;63;2215-2224.
21. Law S, Derry S, and Moore RA. Triptans for acute cluster headache (Review). The Cochrane Collaboration; *Cochrane Database of Systematic Reviews* 2013; Issue 7.

22. Francis G, Becker W, Pringsheim T. Acute and Preventive Pharmacologic Treatment of Cluster Headache. *Neurology* August 3, 2010 75:463-473.
23. Van Vliet J, Bahra A, Martin V, et al. Intranasal Sumatriptan in Cluster Headache, Randomized Placebo-Controlled Double-Blind Study. *Neurology* 2003;60:630-633.
24. Rapoport A, Mathew N, Silberstein S. et al. Zolmitriptan Nasal Spray in the Acute Treatment of Cluster Headache, A double-blind study. *Neurology* 2007;69:821-826.
25. Cittadini E, May A, Straube A, Effectiveness of Intranasal Zolmitriptan in Acute Cluster Headache, A Randomized, Placebo-Controlled, Double-blind Crossover Study. *ArchNeurol.*2006;63. <http://www.archneurol.com/>. Accessed June 2019.
26. American Headache Society. The American Headache Society Position Statement On Integrating New Migraine Treatments Into Clinical Practice. *Headache* 2019;59:1-18.